

HIGH SENSITIVITY C-REACTIVE PROTEIN BENEFITS

DLUWLF= Dr. Levine's Ultimate Weight Loss Formula

Patient #1 (910) (Both the results for this patient are on one page).

4/6/01 Patient's lab work on NIASPAN 2 GRAMS & LIPITOR 80 MG hs CRP 5.9 qunitile 5

12/20/02 Patient's lab work on ADVICOR 2000/40 & DLUWLF hs CRP 0.3 qunitile 1

DISCUSSION:

High sensitivity C-reactive protein levels are a measure of cardiac inflammation and risk of heart disease and plaque rupture. The lowest levels correlate with the lowest risk of cardiovascular disease. This is an independent measure of an individual's risk of heart disease (regardless of the individual's cholesterol levels). The high sensitivity C-reactive protein level test is considered a good test, and produces a high correlation with risk of developing cardiovascular disease. Statin drugs (LIPITOR is the strongest) are known to decrease high sensitivity C-reactive protein levels. This patient was on LIPITOR and had a level associated with a quintile 5, the highest risk of heart disease. The second test shows the patient on ADVICOR which is simply (NIASPAN & MEVACOR together in a pill). The NIASPAN dose is identical, the MEVACOR is much weaker than the LIPITOR. If any change would be expected from the change in medications, it would have been an even higher high sensitivity C-reactive protein level (higher risk of heart disease) **due to the fact MEVACOR is a weaker statin than LIPITOR.** The spectacular improvement in high sensitivity C-reactive protein level on the second test **can only be attributed to the patient using DLUWLF. This shows that DLUWLF has taken the patient from the highest risk of heart disease to the lowest risk.**

Patient #2 (1805)

5/04/01 On LIPITOR 10 mg and NIASPAN 1g : hs-CRP 3.6 mg/l = Q4

Started DLUWLF after this date.

12/06/01 On LIPITOR 10 mg and NIASPAN 2g , DLUWLF : hs-CRP 1.2 mg/l = Q3

2/27/02 On LIPITOR 10 mg and NIASPAN 1.5g , DLUWLF : hs-CRP 0.5 mg/l = Q1

10/30/02 (off LIPITOR) on NIASPAN 1g and DLUWLF : hs-CRP 0.3 mg/l = Q1

DISCUSSION:

This shows the progressive improvement from a high risk hs-CRP level of **Q4 down to a Q1 (lowest risk of cardiovascular disease)**. Note that the patient has remained quintile 1 on the labs repeated 7 months after achieving the quintile 1 and that the actual level has decreased even further from 0.5-0.3 mg/l. Note that LIPITOR, a statin, should lower hs-CRP and it was stopped prior to 10/30/02, the best hs-CRP being on DLUWLF **without LIPITOR**. NIASPAN has no known effect on hs-CRP.

Patient # 3 (1913)

11/19/01 baseline hs-CRP on no medications: hs-CRP 2.4 mg/l = Q4

Note: Patient began DLUWLF after this visit.

Note: Patient began ZOCOR 10-20mg (low dose) one month prior to 11/04/02 due to immobility from knee surgery

11/04/02 Patient on (ZOCOR 10-20mg) & DLUWLF : hs-CRP 0.6 mg/l = Q1

DISCUSSION:

This patient went from a Q4 second highest risk category for heart disease down to the lowest risk Q1. Patient was taking DLUWLF for a year. Applicant has not seen statin drugs (ZOCOR) cause this dramatic drop in hs-CRP even though they can improve hs-CRP. The patient only had 1 month of the lowest dose of ZOCOR, and any drop in hs-CRP from this dose and time period would be expected to be small.

Patient # 4 (928)

11/08/02 Patient on DLUWLF for 3 months : hs-CRP 3.7 mg/l = Q4

4/02/03 on DLUWLF hs-CRP 0.9 mg/l = Q2

DISCUSSION:

This shows the progressive improvement from a high risk hs-CRP level of **Q4 (almost a Q5) down to a Q2 (a much lower risk of cardiovascular disease)**. The patient is not on any statin.

He achieved the improvement on DLUWLF. Note that the patient is only 0.3mg/l away from the 0.6mg/l level that marks the high range of the Q1 range that confers the lowest risk of cardiovascular disease. Note that the measured level went from 3.7 mg/l to 0.9 mg/l a drop of 2.6mg/l. Patient was nearly Q5 with a level of 3.7mg/l as 3.9 mg/l and above is a Q5 (highest risk of heart disease).

E4

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LABORATORY REPORT

Patient Name L [REDACTED]		Patient ID/Hospital ID 910	Room No.	Age 43	Sex M	Physician LEVINE, SCOTT
Page 1	Requisition No. 7158211	Accession No. TP811800H	Lab Ref No. 7158211	Collection Date & Time 04/06/2001 09:27	Log-in Date 04/06/2001	Report Date & Time 04/10/2001 10:00

SS#: [REDACTED] 650

Report Status	Test	Result In Range Out of Range	Units	Reference Range	Site Code
FINAL	CARDIO CRP	5.9 H	MG/L (CALC)	<2.0	TP
Quintile 5 Highest Risk Range 3.9-15.0 mg/L					
This result is associated with the highest risk of coronary heart disease.					
Range for Quintile 1 Lowest Risk					
Cardio CRP <0.7 mg/L					
Niaspan 2gm C.P. for 50					
Servicing Laboratory: TP					

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LABORATORY REPORT

Patient Name L [REDACTED]		Patient ID/Hospital ID 910	Room No.	Age 45	Sex M	Physician LEVINE, SCOTT
Page 2	Requisition No. 7159735	Accession No. TP040003R	Lab Ref No. 7159735	Collection Date & Time 12/20/2002 11:25	Log-in Date 12/20/2002	Report Date & Time 12/22/2002 05:00

SS#: [REDACTED] 60

Report Status	Test	Result In Range Out of Range	Units	Reference Range	Site Code
FINAL	CBC (INCLUDES DIFF/PLT) (CONTINUED)				
CARDIO CRP INTERPRETATION		0.3	MG/L (CALC)	SEE BELOW	TP
CARDIOVASCULAR RISK		1.4	Rel. Risk		
The Relative Risk of 1.4 for cardiovascular disease is based on both Cardio CRP and Total Cholesterol/HDL Cholesterol results. Individuals with the lowest risk have a relative risk of 1.0. Other risk factors include age, gender, blood pressure, smoking and diabetes.					
This patient's Cardio CRP result alone is associated with the Lowest Risk of cardiovascular disease. This patient's Total Cholesterol / HDL Cholesterol ratio alone is associated with a Low Risk of cardiovascular disease. These risk estimates are based on population studies of adults 20 years and older.					
CRP 0.1					
Advicor 1000/200					

E5

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LABORATORY REPORT

Patient Name D [REDACTED]		Patient ID/Hospital ID 1805		Room No.	Age 33	Sex M	Physician LEVINE, SCOTT
Page 1	Requisition No. 7158300	Accession No. TP2305331	Lab Ref No. 7158300	Collection Date & Time 05/04/2001 09:40		Log-in Date 05/04/2001	Report Date & Time 05/08/2001 06:00

Remarks

SS#: [REDACTED]

Report Status	Test	Result		Units	Reference Range	Site Code
		In Range	Out of Range			
CARDIO CRP RISK			3.6 H	MG/L (CALC)	<2.0	TP
Quintile 4 High Risk Range 2.0-3.8 mg/L						
This result is associated with a high risk of coronary heart disease.						
Range for Quintile 1 Lowest Risk						

Cardio CRP <0.7 mg/L						

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LABORATORY REPORT

Patient Name D. [REDACTED]		Patient ID/Hospital ID 1805		Room No.	Age 34	Sex M	Physician LEVINE, SCOTT
Page 1	Requisition No. 7158916	Accession No. TP306943L	Lab Ref No. 7158916	Collection Date & Time 12/05/2001 10:07	Log-In Date 12/05/2001	Report Date & Time 12/06/2001 06:00	

Remarks

SS#: [REDACTED]

Report Status	Test	Result	Units	Reference Range	Site Code
		In Range Out of Range			
COMPREHENSIVE METABOLIC PANEL					
	GLUCOSE	80	MG/DL	65-109	TP
	UREA NITROGEN (BUN)	13	MG/DL	7-25	
	CREATININE	1.1	MG/DL	0.5-1.4	
	BUN/CREATININE RATIO	12	(CALC)	6-25	
	SODIUM	141	MMOL/L	135-146	
	POTASSIUM	4.3	MMOL/L	3.5-5.3	
	CHLORIDE	104	MMOL/L	98-110	
	CARBON DIOXIDE	22	MMOL/L	21-33	
	CALCIUM	9.4	MG/DL	8.5-10.4	
	PROTEIN, TOTAL	6.6	G/DL	6.0-8.3	
	ALBUMIN	4.4	G/DL	3.7-5.1	
	GLOBULIN	2.2	G/DL (CALC)	2.2-4.2	
	ALBUMIN/GLOBULIN RATIO	2.0	(CALC)	0.8-2.0	
	BILIRUBIN, TOTAL	0.8	MG/DL	0.2-1.5	
	ALKALINE PHOSPHATASE	94	U/L	20-125	
	AST	26	U/L	2-50	
	ALT	21	U/L	2-60	
CBC (INCLUDES DIFF/PLT)					
	WHITE BLOOD CELL COUNT	6.7	THOUS/MCL	3.8-10.8	TP
	RED BLOOD CELL COUNT	5.13	MILL/MCL	4.20-5.80	
	HEMOGLOBIN	16.2	G/DL	13.2-17.1	
	HEMATOCRIT	48.6	%	38.5-50.0	
	MCV	94.7	FL	80.0-100.0	
	MCH	31.6	PG	27.0-33.0	
	MCHC	33.3	G/DL	32.0-36.0	
	RDW	12.9	%	11.0-15.0	
	PLATELET COUNT	181	THOUS/MCL	140-400	
	ABSOLUTE NEUTROPHILS	4228	CELLS/MCL	1500-7800	
	ABSOLUTE LYMPHOCYTES	1682	CELLS/MCL	850-3900	
	ABSOLUTE MONOCYTES	449	CELLS/MCL	200-950	
	ABSOLUTE EOSINOPHILS	302	CELLS/MCL	50-550	
	ABSOLUTE BASOPHILS	40	CELLS/MCL	0-200	
	NEUTROPHILS	63.1	%		
	LYMPHOCYTES	25.1	%		
	MONOCYTES	6.7	%		
	EOSINOPHILS	4.5	%		
	BASOPHILS	0.6	%		
	CARDIO CRP	1.2	MG/L	<2.0	TP
	RISK		(CALC)		

CARDIO CRP (CONTINUED)

Quintile 3 Moderate Risk Range 1.2-1.9 mg/L

This result is associated with a moderate risk of coronary heart disease.

Range for Quintile 1 Lowest Risk

Cardio CRP <0.7 mg/L

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Patient Name D [REDACTED]		Patient ID/Hospital ID 1805	Room No.	Age 34	Sex M	Physician LEVINE, SCOTT
Page 2	Requisition No. 7159103	Accession No. TP508840M	Lab Ref No. 7159103	Collection Date & Time 02/27/2002 09:25	Log-in Date 02/27/2002	Report Date & Time 02/28/2002 14:00
Remarks						

SS#: [REDACTED]

Report Status	Test	Result In Range Out of Range	Units	Reference Range	Site Code
FINAL	CARDIO CRP (CONTINUED)				
	CARDIO CRP RISK	0.5	MG/L (CALC)	<2.0	TP
<p>Cardio CRP:</p> <p>Quintile 1 Lowest Risk Range <0.7 mg/L</p> <p>TC/HDL-C Ratio:</p> <p>Quintile 1 Lowest Risk Range <3.34</p> <p>RELATIVE RISK</p> <p>Based on Cardio CRP and Total Cholesterol/HDL-C stratification, the relative risk for a cardiovascular event is equivalent to that of individuals in the lowest risk quintiles for both of these tests.</p>					

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LABORATORY REPORT

Patient Name D [REDACTED] K		Patient ID/Hospital ID 1805		Room No.	Age 35	Sex M	Physician LEVINE, SCOTT
Page 2	Requisition No. 7159591	Accession No. TP269932Q	Lab Ref No. 7159591	Collection Date & Time 10/30/2002 09:15	Log-in Date 10/30/2002	Report Date & Time 10/31/2002 10:00	

Remarks

SS# [REDACTED]

Report Status	Test	Result In Range Out of Range	Units	Reference Range	Site Code
FINAL					
CBC (INCLUDES DIFF/PLT) (CONTINUED)					
CARDIO CRP		0.3	MG/L	SEE BELOW	TP
INTERPRETATION			(CALC)		
	CARDIOVASCULAR RISK	1.0	Rel.Risk		
<p>The Relative Risk of 1.0 for cardiovascular disease is based on both Cardio CRP and Total Cholesterol/HDL Cholesterol results. Individuals with the lowest risk have a relative risk of 1.0. Other risk factors include age, gender, blood pressure, smoking and diabetes.</p> <p>This patient's Cardio CRP result alone is associated with the Lowest Risk of cardiovascular disease. This patient's Total Cholesterol/HDL Cholesterol ratio alone is associated with the Lowest Risk of cardiovascular disease. These risk estimates are based on population studies of adults 20 years and older.</p>					

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Patient Name D [REDACTED] M		Patient ID/Hospital ID 1913	Room No.	Age 49	Sex M	Physician LEVINE, SCOTT
Page 1	Requisition No. 7158878	Accession No. TP082030L	Lab Ref No. 7158878	Collection Date & Time 11/19/2001 12:27	Log-in Date 11/19/2001	Report Date & Time 11/21/2001 05:00

Remarks

SS#: [REDACTED]

Report Status	Test	Result	Units	Reference Range	Site Code
		In Range Out of Range			
FINAL	COMPREHENSIVE METABOLIC PANEL				
	GLUCOSE	76			TP



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Patient Name D [REDACTED] M		Patient ID/Hospital ID 1913	Room No.	Age 49	Sex M	Physician LEVINE, SCOTT
Page 2	Requisition No. 7158878	Accession No. TP082030L	Lab Ref No. 7158878	Collection Date & Time 11/19/2001 12:27	Log-in Date 11/19/2001	Report Date & Time 11/21/2001 05:00

Remarks

SS#: [REDACTED]

Report Status	Test	Result	Units	Reference Range	Site Code
		In Range Out of Range			
FINAL	CARDIO CRP (CONTINUED)				
	Quintile 4 High Risk	Range 2.0-3.8 mg/L			
	This result is associated with a high risk of coronary heart disease.				
	Range for Quintile 1	Lowest Risk			
	Cardio CRP	<0.7 mg/L			

Q4

CARDIO CRP RISK

Q4

2.4 H

MG/L (CALC)

<2.0

TP

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LABORATORY REPORT

Patient Name D [REDACTED] M		Patient ID/Hospital ID 1913		Room No.	Age 50	Sex M	Physician LEVINE, SCOTT
Page 2	Requisition No. 7159606	Accession No. TP332070Q	Lab Ref No. 7159606	Collection Date & Time 11/04/2002 09:13	Log-in Date 11/04/2002	Report Date & Time 11/05/2002 06:00	

Remarks

SS#: [REDACTED]

Report Status	Test	Result In Range Out of Range	Units	Reference Range	Site Code
FINAL	CBC (INCLUDES DIFF/PLT) (CONTINUED)				
CARDIO CRP INTERPRETATION		0.6	MG/L (CALC)	SEE BELOW	TP
CARDIOVASCULAR RISK		1.4	Rel. Risk		
<p>The Relative Risk of 1.4 for cardiovascular disease is based on both Cardio CRP and Total Cholesterol/HDL Cholesterol results. Individuals with the lowest risk have a relative risk of 1.0. Other risk factors include age, gender, blood pressure, smoking and diabetes.</p> <p>This patient's Cardio CRP result alone is associated with the Lowest Risk of cardiovascular disease. This patient's Total Cholesterol / HDL Cholesterol ratio alone is associated with a Low Risk of cardiovascular disease. These risk estimates are based on population studies of adults 20 years and older.</p>					
'TP' Indicates testing site: QUEST DIAGNOSTICS-TAMPA 4225 E. FOWLER AVE TAMPA FL 33617 (813) 972-7100					
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Remarked
Q1

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LABORATORY REPORT

Patient Name: HARRIS, SCOTT		Patient ID/Hospital ID: 928		Room No.:	Age: 44	Sex: M	Physician: LEVINE, SCOTT
Page 1	Requisition No. 7159621	Accession No. TP421540Q	Lab Ref No. 7159621	Collection Date & Time 11/08/2002 11:36	Log-in Date 11/08/2002	Report Date & Time 11/12/2002 06:00	

Remarks

SS#: 40-75

Report Status	Test	Result	Units	Reference Range	Site Code
		In Range	Out of Range		
PATIENT DATE OF BIRTH: 07/30/1958					
	LIPOPROTEIN (a)	12		MG/DL	EZ
		Reference Range:			
		30 OR LESS			
	CARDIO CRP INTERPRETATION	Q4 3.7		MG/L (CALC)	TP
	This Cardio CRP result is between 2.0-3.8 mg/L. This range is associated with a High risk of cardiovascular disease. The range associated with the Lowest Risk of cardiovascular disease is 0-0.6 mg/L.				
'EZ'	Indicates testing site: QUEST DIAGNOSTICS - NICHOLS INSTITUTE 33608 ORTEGA HWY SAN JUAN CAPISTRAN CA 92690 (800) 553-5445				
'TP'	Indicates testing site: DA FISHER MD; RE REITZ MD QUEST DIAGNOSTICS-TAMPA 4225 E. FOWLER AVE TAMPA FL 33617 (813) 972-7100				
>> END OF REPORT <<					

P. notified 11/12

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LABORATORY REPORT

Patient Name HUNTER, SCOTT S		Patient ID/Hospital ID 928		Room No.	Age 44	Sex M	Physician LEVINE, SCOTT
Page 2	Requisition No. 7159947	Accession No. TP524648S	Lab Ref No. 7159947	Collection Date & Time 03/31/2003 11:54	Log-in Date 03/31/2003	Report Date & Time 04/02/2003 06:00	

Remarks

SS#: 75

Report Status	Test	Result In Range Out of Range	Units	Reference Range	Site Code
FINAL	CBC (INCLUDES DIFF/PLT) (CONTINUED)				
	CARDIO CRP	0.9	MG/L	SEE BELOW	TP
<p>EFFECTIVE APRIL 14, 2003, CARDIO CRP WILL BE REPORTED IN ACCORDANCE WITH THE NEW AMERICAN HEART ASSOCIATION/CENTER FOR DISEASE CONTROL AND PREVENTION GUIDELINES PUBLISHED IN THE JANUARY 28, 2003, ISSUE OF CIRCULATION (2003:107:499-511).</p>					
INTERPRETATION (CALC)					
CARDIOVASCULAR RISK 1.7 Rel.Risk					
<p>The Relative Risk of 1.7 for cardiovascular disease is based on both Cardio CRP and Total Cholesterol/HDL Cholesterol results. Individuals with the lowest risk have a relative risk of 1.0. Other risk factors include age, gender, blood pressure, smoking and diabetes.</p>					
<p>This patient's Cardio CRP result alone is associated with a Low Risk of cardiovascular disease. This patient's Total Cholesterol/HDL Cholesterol ratio alone is associated with a Low Risk of cardiovascular disease. These risk estimates are based on population studies of adults 20 years and older.</p>					
HEMOGLOBIN A1c	5.3		% TOTAL HGB	NON-DIABETIC: <6.0%	TP

'TP' Indicates testing site: QUEST DIAGNOSTICS-TAMPA
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